DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Display Date 4-27-01
Publication Date 4-30-01
Certifier Skeese

Food and Drug Administration

21 CFR Parts 520, 522, and 556

Animal Drugs, Feeds, and Related Products; Sarafloxacin for Poultry; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing the portions reflecting approval of two new animal drug applications (NADAs) for which the sponsor has requested withdrawal of approval. The NADAs provide for use of sarafloxacin to treat poultry. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of two NADAs sponsored by Abbott Laboratories.

DATES: This rule is effective April 30, 2001.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of two NADAs held by Abbott Laboratories, North Chicago, IL 60064. The NADAs provide for use of sarafloxacin to treat poultry. NADA 141–017 provides for the use of SaraFlox® (sarafloxacin hydrochloride) WSP and is under § 520.2095 (21 CFR 520.2095) and NADA 141–018 provides for the use of SaraFlox® (sarafloxacin hydrochloride) Injection and is under § 522.2095 (21 CFR 522.2095). Relevant information concerning tolerances for residues of sarafloxacin in edible tissues of poultry is under § 556.594 (21 CFR 556.594).

NFR 1

Abbott Laboratories requested withdrawal of approval in response to safety questions raised by FDA regarding the products.

No other NADAs for use of sarafloxacin have been approved. Therefore, in accordance with the notice of withdrawal of approvals, FDA is amending the regulations to remove §§ 520.2095, 522.2095, and 556.594 effective April 30, 2001.

The agency has determined under 21 CFR 25.33(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Parts 520 and 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Food and Drug Administration and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, and 556 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.2095 [Removed]

2. Section 520.2095 *Sarafloxacin soluble powder* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

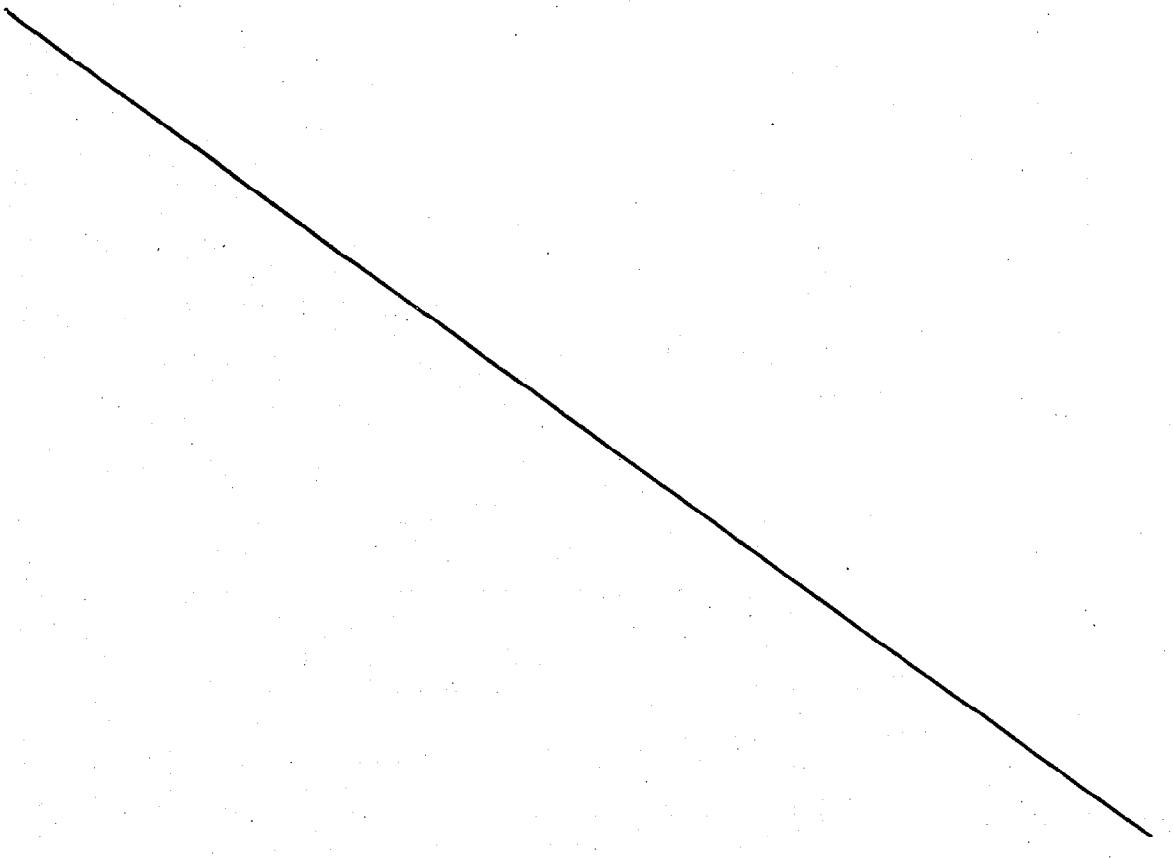
§ 522.2095 [Removed]

4. Section 522.2095 *Sarafloxacin solution for injection* is removed.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

5. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.



§ 556.594 [Removed]

6. Section 556.594 *Sarafloxacin* is removed.

Dated: 4/17/01
April 17, 2001.

Stephen F. Sundlof,
Director, Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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